(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 April 2005 (21.04.2005)

PCT

(10) International Publication Number
WO 2005/034778 A1

(51) International Patent Classification[7]: A61B 17/32

(21) International Application Number:
PCT/US2004/024280

(22) International Filing Date: 28 July 2004 (28.07.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/503,839 18 September 2003 (18.09.2003) US

(71) Applicant *(for all designated States except US)*: **FACET TECHNOLOGIES, LLC** [US/US]; 1850 Parkway Place, Suite 900, Marietta, GA 30067 (US).

(72) Inventors; and

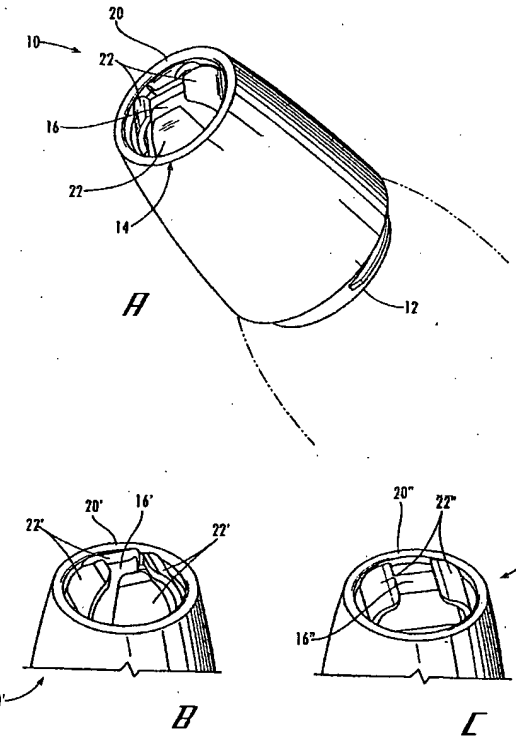
(75) Inventors/Applicants *(for US only)*: **FLYNN, Stephen** [US/US]; 605 Wheatleigh Curve, Peachtree City, GA 30269 (US). **LEVAUGHN, Richard, W.** [US/US]; 532 Sullivan Road, Newnan, GA 30265 (US). **RUF, Christopher, J.** [US/US]; 2120 Ithica Drive, Marietta, GA 30067 (US). **KENNEDY, Gwenn, E.** [US/US]; 5 North Lakeside Drive, Ellenwood, GA 30294 (US). **LIPOMA, Michael, V.** [US/US]; 4066 Argonne Court, Villa Rica, GA 30180 (US). **SALLERAS, Juan, D.** [US/US]; 14430 Wyndham Farms Drive, Alpharetta, GA 30004 (US). **HOLZAEPFEL, Jac** [US/US]; 106 Fen Way, Peachtree City, GA 30269 (US). **RAMOS, Sylvia** [US/US]; 1850 Parkway Place, Suite 900, Marietta, GA 30067 (US).

(74) Agent: **GROFF, Bradley, K.**; Gardner Groff, P.C., Papel Mill Village, Building 23, 600 Village Trace, Suite 300, Marietta, GA 30067 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,

[Continued on next page]

(54) Title: LANCING DEVICE END CAP WITH FLEXING CONTACT ELEMENTS



(57) Abstract: An endcap (10) for a lancing device having at least one flexible finger (22) for manipulating tissue at the sampling site. Pressing the lancing device against the skin at the lancing site flexes the finger (22) inwardly or outwardly to pinch or tension the skin, directing subcutaneous blood-flow toward the sampling site and preventing premature wound closure.

WO 2005/034778 A1

GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

LANCING DEVICE END CAP WITH FLEXING CONTACT ELEMENTS

Cross-Reference to Related Application

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 60/503,839, filed September 18, 2003, the entirety of which is hereby incorporated herein by reference for all purposes.

Technical Field

[0002] The present invention relates generally to medical devices and procedures, and more particularly to lancing devices for sampling blood or other bodily fluids. The invention more particularly relates to an end cap for use in conjunction with a lancing device that allows for the collection of an increased volume of blood or bodily fluid to be sampled.

Background of the Invention

[0003] Many medical procedures require puncturing of the skin, and sometimes underlying tissues, of a human or animal subject. For example, a sharp lancet tip is commonly used to puncture the subject's skin for sampling of blood or other body fluid, as for example in blood glucose monitoring by diabetics. Generally, lancet blades or needles are much thinner than traditional hypodermic syringe needles, and therefore result in less pain to the patient. A lancet having a sharp lancing tip typically is mounted, permanently or releasably, to the drive mechanism of a lancing device. The drive mechanism includes one or more springs, cams, motors, or other mechanism(s) for moving the lancing tip from a retracted position shielded within a housing of the lancing device to an extended position outside of the housing for lancing the subject's skin. The lancing device may also include a cocking mechanism for arming the drive mechanism, and/or a triggering mechanism for firing the device. The housing of the lancing device typically includes an endcap with an opening through which the lancing tip extends in its extended position. The endcap may be releasably or permanently attached to the remainder of the housing, or can comprise an integral part of the housing.

[0004] One common problem that has been found to exist with many known lancets and lancing devices is the closure of the puncture site before an adequate volume of blood has been collected. Premature closure of the puncture requires additional blood to be drawn from the patient, often in a separate and sometimes less desirable location, resulting in an increase in pain and stress to the subject. Costs also increase, as multiple lancets are required to acquire an adequate sample. This is particularly the case when alternate sampling sites other than the fingertips, such as for example the forearm or earlobe, are lanced. Lancing at such alternate sampling sites may be desirable because repeated lancing of the fingertips can result in callous formation, leading to less consistent sampling and decreased sensitivity of the fingertips. In addition, the fingertips have a greater density of nerve endings than alternate sampling sites, resulting in greater pain sensation from fingertip lancing than lancing at alternate sites. To increase patient compliance with a prescribed sampling regimen, it is desirable to minimize pain resulting from the lancing operation. However, because alternate sites typically contain a lower density of capillaries or a deeper capillary bed than the fingertips, alternate sampling sites often yield insufficient sample sizes or are prone to premature closure.

[0005] Attempts have been made to provide lancing devices that inhibit premature closure of the puncture site and yield increased sample size. Such attempts have included ~~the use of a stimulator member slidably mounted to the housing for cyclically pumping~~ around the puncture site to "milk" the wound. Although utilizing the aforementioned pumping sequence may allow a larger sample to be collected before closure of the puncture site, occasionally a sample is still insufficient, and another lancing operation to collect blood or analytic fluid is required. Additionally, the repeated application and release of pressure from such pumping can result in contact between the sample and the lancing device, smearing and/or contaminating the sample and necessitating another lancing operation, and/or can lead to bruising of the tissue surrounding the sampling site. Also, the provision of a translationally mounted stimulator member results in increased complexity and cost of the lancing device.

[0006] Thus it can be seen that needs exist for improved lancing devices and methods to facilitate increased sample volume of blood or other analytic fluid, and to prevent premature closure of the wound at the sampling site. Needs further exist for such mechanisms and methods that are readily adaptable to current lancing devices and procedures, and which can be utilized for lancing at fingertip as well as alternate sample collection sites.

Summary of the Invention

[0007] In example forms, the present invention is an endcap for a lancing device that enables collection of an increased volume of blood or other body fluid to be sampled from a sampling site of a human or animal subject. The device of the present invention is suitable for use at fingertip sampling sites, but is also well suited for use at alternate sampling sites such as the forearm and/or earlobe. In further embodiments, the invention is a sampling method for increasing collected sample size of blood or other body fluid from a sampling site.

[0008] In one aspect, the present invention is an endcap for a lancing device. The endcap preferably has a first end for connection to the lancing device, a second end for contacting the skin around a sampling site, and at least one flexible finger extending toward the second end for contacting and manipulating the skin at the sampling site.

[0009] In another aspect, the invention is a lancing device for collecting a sample of body fluid from a sampling site on the skin of a subject. The lancing device preferably includes a lancet and a housing comprising an endcap, the lancet being movable between a first position within the housing and a second position wherein at least a sharp tip portion of the lancet extends through the endcap. The endcap preferably includes at least one flexible contact element for contacting and manipulating the skin at the sampling site.

[00010] In still another aspect, the invention is a lancing device having an opening for passing at least a sharp tip portion of a lancet therethrough, and a contact face surrounding the opening for contact against the skin around a sampling site. The lancing

device preferably also includes at least one flexible member having a free end extending beyond the contact face in its unflexed state.

[00011] In another aspect, the invention is a method of lancing skin to collect a fluid sample, the method preferably including the steps of pressing a lancing device into contact with the skin adjacent a sampling site, lancing the skin at the sampling site, and actuating at least one flexible finger to flex and manipulate tissue adjacent the sampling site.

[00012] These and other aspects, features and advantages of the invention will be understood with reference to the drawing figures and detailed description herein, and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

Brief Description of the Drawings

[00013] **FIGURES 1a-1c** show perspective views of endcaps for a lancing device, according to example embodiments of the present invention.

[00014] **FIGURES 2a and 2b** show perspective and side views of an endcap for a lancing device according to another example embodiment of the present invention.

[00015] **FIGURES 3a and 3b** show perspective and side views of an endcap for a lancing device according to a further example embodiment of the present invention.

[00016] **FIGURES 4a and 4b** show perspective and side views of an endcap for a lancing device according to another example embodiment of the present invention.

[00017] **FIGURES 5a and 5b** show perspective and side views of an endcap for a lancing device according to still another example embodiment of the present invention.

Detailed Description of Example Embodiments

[00018] The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

[00019] With reference now to the drawing figures, Figures 1a, 1b and 1c show example embodiments of an endcap 10 for a lancing device according to the present invention (corresponding features of the embodiments of Figs. 1b and 1c are indicated with single prime and double-prime reference numbers, respectively). The endcap 10 preferably comprises a first end 12 for releasable or permanent attachment to the remainder of a housing of a lancing device. Alternatively, the endcap forms an integral part of the housing of the lancing device. The endcap 10 can be adapted for use with any of a variety of standard, commercially-available or later-developed lancing devices, by appropriate configuration of coupling or attachment features of the first end 12. The second end 14 of the endcap 10 preferably defines the opening 16 through which the sharp lancet tip projects in its extended position to penetrate the skin at the intended sampling site.

[00020] In the depicted embodiment, the opening 16 is a generally square opening formed at or near the center of the second end 14 of the endcap 10. In alternate embodiments, the opening is a slot or an opening of circular, triangular, rectangular, polygonal or other shape. The second end 14 of the endcap 10 preferably comprises a contact ring or face 20, for placement against the skin around the sampling site. One or more flexible fingers 22 extend from the endcap adjacent to the opening 16, projecting obliquely forward and curving inward from the periphery of the opening. Four flexible fingers 22 (two opposed pairs) project from the four sides of the opening 16 in the embodiments of Figs. 1a and 1b, and two flexible fingers project from opposed sides of the opening in the embodiment of Fig. 1c. The flexible fingers 22 optionally taper from wider and/or thicker at their root ends where they are connected to the endcap to narrower and/or thinner at their free ends, to provide progressively increasing flexure toward the free ends. Alternatively or additionally, the fingers 22 comprise one or more thin regions, notches or other points of weakness, which act as a hinge point during flexure. The free edges or tips of the fingers 22 are optionally turned forward, as shown in Figs. 1b and 1c, and have an angled chisel edge to better engage the skin around the sampling site. The flexible fingers are preferably formed of an engineering or medical-grade polymer, plastic or other flexible, resilient material. The fingers 22 are preferably formed as integral portions of a unitary endcap, as by injection molding or the like; or alternatively are separately formed and attached to the body of the endcap by adhesive, welding, solvent or thermal bonding, snap-fittings, couplings, connectors, or other attachment means.

[00021] The second end 14 of the endcap 10 is pressed against the subject's skin around the sampling site prior to, during, and/or after lancing, causing the fingers 22 to flex inwardly until the contact ring 20 is pressed firmly against the skin, with the fingers engaging and pinching the skin at the sampling site to direct subcutaneous blood toward the sampling site. Maintaining or applying pressure of the endcap against the skin around the sampling site during and after lancing further assists in expressing blood out of the

wound for sample collection, and causes the skin to bulge slightly to prevent premature closure of the sampling site wound.

[00022] Figures 2a and 2B show an endcap 30 for a lancing device according to another embodiment of the present invention. Lengthwise slits through at least a forward portion of the endcap 30 proximal the second end 32 divide the endcap into a plurality of fingers, at least one of which is a compressible finger. These fingers of the endcap 30 are preferably tapered inwardly toward the second end 32 of the endcap, and are formed of a flexible resilient material. In the depicted embodiment, four slits divide the endcap into four fingers, two of which are compressible fingers 34, and two of which are non-compressible fingers 36. The compressible fingers 34 preferably comprise an angled or accordion-folded hinged section formed of flexible resilient material, which compresses when the endcap 30 is pressed against the subject's skin. The non-compressible fingers 36 preferably comprise generally flat forward faces for contact with the subject's skin, and defining an opening therebetween for allowing passage of the sharp lancet tip. The compressible fingers 34 are preferably longer than the non-compressible fingers 36, and extend beyond the non-compressible fingers in the direction of the second end 32 of the endcap 30. When the second end 32 of the endcap 30 is pressed against the subject's skin at the sampling site, the compressible fingers 34 compress until the forward faces of ~~the non-compressible fingers 36 are firmly pressed against the skin. The inward taper of~~ the endcap 30 coupled with the compression of the compressible fingers 34 preferably causes the fingers 34, 36 to flex inwardly upon pressing the endcap against the skin, pooling blood at the sampling site prior to lancing, and helping to express blood from the sampling site and prevent wound closure after lancing.

[00023] Figures 3a and 3b show an endcap 50 for a lancing device according to another embodiment of the present invention. The second end 52 of this endcap embodiment comprises a plurality of flexible fingers 54, which taper outwardly toward the second end of the endcap. The free ends of the fingers 54 optionally comprise contact faces that are obliquely angled, tapering outwardly and away from the first end of the

endcap. An opening is preferably defined between the contact faces for passing the sharp lancet tip. As the second end 52 of the endcap 50 is pressed against the subject's skin around the sampling site, the fingers 54 preferably flex outwardly, tensioning the skin at the sampling site. Maintaining pressure on the lancing device after lancing thus tends to pull the sampling site wound open, preventing premature closure. If the sharp lancet tip is a blade having a transverse penetration edge (as opposed to a needle having a pointed penetration tip), it is preferable to align the blade in the lancing device such that the fingers apply tension to the skin perpendicular to the cutting edge of the blade, thereby further enhancing the tendency to open the wound. Optionally, one or more of the fingers 54 is configured to be more or less flexible than one or more other fingers, to impart tension to the skin in a specified direction. For example, in the depicted embodiment, a first opposed pair of fingers has a greater thickness (and thereby a lower degree of flexure upon application of pressure) than a second opposed pair of fingers oriented perpendicular to the first pair. In this manner, application of pressure causes a greater degree of flexure of the second pair of fingers, tensioning the skin to a greater extent in the direction extending between the fingers of the second pair.

[00024] Figures 4a and 4b show an endcap 70 for a lancing device according to another embodiment of the present invention. The second end 72 of this endcap ~~embodiment comprises a plurality of fingers, at least one of which is a flexing finger. In the~~ depicted embodiment, an alternating array of four flexing fingers 74 and four non-flexing fingers 76 is provided. In alternate embodiments, all of the fingers are flexing fingers. The flexing fingers 74 are preferably tapered or biased obliquely outwardly toward their free ends, and preferably include a barb or projection 78 adjacent their free ends. A collett ring 80 is slideably mounted around the flexing fingers 74, between the barbs 78 and a retaining flange 82 proximal the first end of the endcap 70, as indicated by directional arrow 84. Sliding the collett ring 80 toward the second end 72 of the endcap 70 causes the flexing fingers 74 to flex inwardly, and sliding the collett ring toward the first end of the endcap allows the flexing fingers to return to their outwardly tapered positions. The collett

ring optionally comprises a ribbed or knurled outer surface for improved manual gripping. The non-flexing fingers 76 optionally comprise flat or tapered contact faces at their free ends for contacting the subject's skin around the sampling site, and defining an opening therebetween for allowing passage of the lancet tip. The flexing fingers 74 are preferably longer than the non-flexing fingers 76, and extend beyond the non-flexing fingers in the direction of the second end 72 of the endcap 70. The second end 72 of the endcap is pressed against the skin at the sampling site, the skin is lanced, and the collett ring 80 is slid toward the second end of the endcap (prior to, during or after the lancing step) to move the flexing fingers 74 inwardly to direct subcutaneous blood toward the sampling site wound, where it is expressed for sample collection.

[00025] Figures 5a and 5b show an endcap 90 for a lancing device according to still another embodiment of the present invention. The second end 92 of this endcap embodiment comprises a contact face 94 defining a generally central opening 96 for passage of the lancet tip therethrough. At least one (four are shown) flexible finger(s) 98 are attached to the endcap proximal the first end of the endcap, and have free ends projecting beyond the contact face 94 at the second end 92 of the endcap. In the depicted embodiment, the fingers 98 are outwardly bowed, with their free ends tapered inwardly. Pressing the second end 92 of the endcap 90 against the skin around the sampling site ~~causes the fingers to bow further and thereby bends their free ends further inwardly,~~ compressing the skin at the sampling site to direct blood toward the wound and help prevent premature closure of the wound. In alternate embodiments, the fingers 98 are bowed inwardly with their free ends tapered outwardly, such that pressing the endcap against the skin around the sampling site bends the free ends further outwardly and tensions the skin to prevent wound closure. In still further embodiments, one or more fingers are bowed outwardly and tapered inwardly at their free ends, and one or more fingers are bowed inwardly and tapered outwardly at their free ends, such that pressure against the skin compresses the skin in one direction and tensions the skin in another direction.

[00026] In a preferred method of operation according to the present invention, the second end of the endcap of the lancing device is pressed into contact with the subject's skin at the sampling site, the skin is lanced, and the sample is collected. In certain embodiments, the fingers of the endcap are actuated (as by compression, manipulation of a collett ring, or otherwise) to flex inwardly and/or outwardly, and thereby compress, tension, slide in contact with, and/or otherwise manipulate the tissue at and/or around the sampling site, prior to lancing of the skin. Alternatively or additionally, the fingers are acutated to flex inwardly and/or outwardly to manipulate the tissue at and/or around the sampling site during and/or after lancing of the skin. In this manner, subcutaneous blood can be directed by action of the fingers to pool in the area of the sampling site prior to or during lancing, and/or the blood can be expressed out of the wound by action of the fingers during or after lancing, and/or the wound can be maintained open by the fingers to prevent premature closure.

[00027] While the invention has been described with reference to preferred and example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

CLAIMS

What is claimed is:

1. An endcap for a lancing device, the endcap comprising a first end for connection to the lancing device, a second end for contacting the skin around a sampling site, and at least one flexible finger extending toward the second end for contacting and manipulating the skin at the sampling site.

2. The endcap of Claim 1, wherein the second end of the endcap defines an opening for passing a sharp lancet tip, and wherein the at least one flexible finger comprises a first pair of fingers extending from adjacent the opening and projecting obliquely forward and curving inward from the periphery of the opening.

3. The endcap of Claim 2, further comprising a second pair of fingers extending inward from the periphery of the opening, generally perpendicular to the first pair of fingers.

4. The endcap of Claim 2, wherein the fingers have sharp distal tips for engaging the skin at the sampling site.

5. The endcap of Claim 1, wherein the at least one flexible finger comprises an opposed pair of compressible fingers having a hinged section that compresses when the endcap is pressed against the sampling site.

6. The endcap of Claim 5, further comprising a pair of non-compressible fingers defining a lancet opening therebetween, wherein the compressible fingers are longer than the non-compressible fingers.

7. The endcap of Claim 1, wherein the at least one flexible finger comprises an opposed pair of outwardly flexing fingers.

8. The endcap of Claim 7, wherein the opposed pair of outwardly flexing fingers comprise contact faces that are obliquely angled and taper outwardly away from the first end of the endcap.

9. The endcap of Claim 1, wherein the at least one flexible finger comprises at least one flexing finger tapered obliquely outwardly toward its free end, and further comprising a collett ring slideably mounted around the at least one flexing finger.

10. The endcap of Claim 9, further comprises at least one non-flexing finger having a forward contact face for contacting the skin at the sampling site.

11. The endcap of Claim 1, wherein the at least one flexible finger comprises an opposed pair of outwardly-bowed, inwardly-flexing fingers.

12. The endcap of Claim 11, further comprising a contact face between the pair of outwardly-bowed, inwardly-flexing fingers, and wherein free distal ends of the fingers extend beyond the contact face.

13. A lancing device for collecting a sample of body fluid from a sampling site on the skin of a subject, said lancing device comprising a lancet and a housing comprising an endcap, the lancet being movable between a first position within the housing and a second position wherein at least a sharp tip portion of the lancet extends through the endcap, wherein the endcap comprises at least one flexible contact element for contacting and manipulating the skin at the sampling site.

14. The lancing device of Claim 13, wherein the at least one flexible contact element ~~comprises two opposed curved flexible members.~~

15. The lancing device of Claim 13, wherein the at least one flexible contact element comprises an opposed pair of compressible members having a hinged section that compresses when pressed against the sampling site.

16. The lancing device of Claim 13, wherein the at least one flexible contact element comprises an opposed pair of outwardly flexing members.

17. The lancing device of Claim 13, wherein the at least one flexible contact element comprises at least one flexing member tapered obliquely outwardly toward its free end, and further comprising a collett ring slideably mounted around the at least one flexing member.

18. The lancing device of Claim 13, wherein the at least one flexible contact element comprises an opposed pair of outwardly-bowed, inwardly-flexing members.

19. A lancing device having an opening for passing at least a sharp tip portion of a lancet therethrough, and a contact face surrounding said opening for contact against the skin around a sampling site, the lancing device further comprising at least one flexible member having a free end extending beyond the contact face in its unflexed state.

20. A method of lancing skin to collect a fluid sample, the method comprising:

pressing a lancing device into contact with the skin adjacent a sampling site;

lancing the skin at the sampling site; and

actuating at least one flexible finger to flex and manipulate tissue adjacent the sampling site.

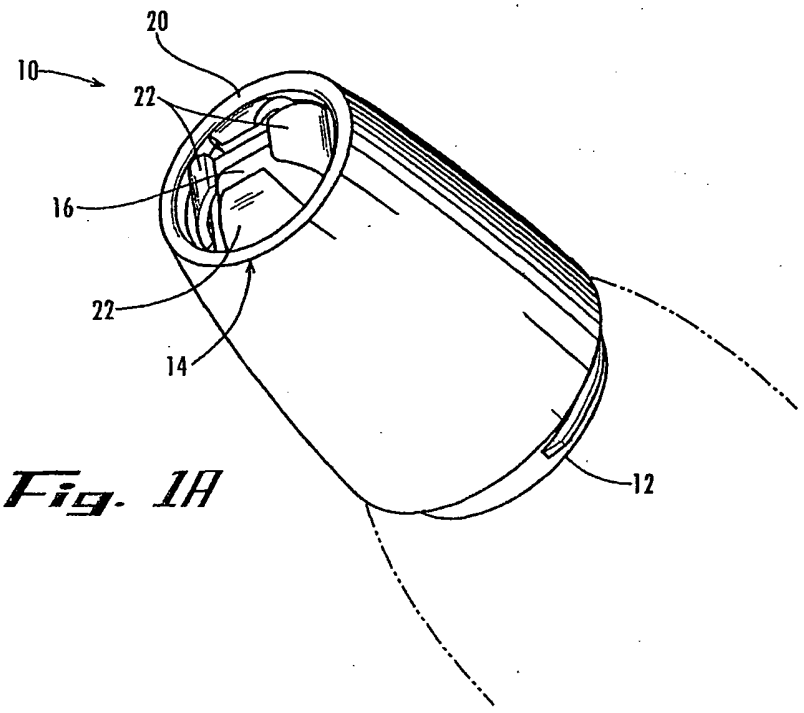


Fig. 1A

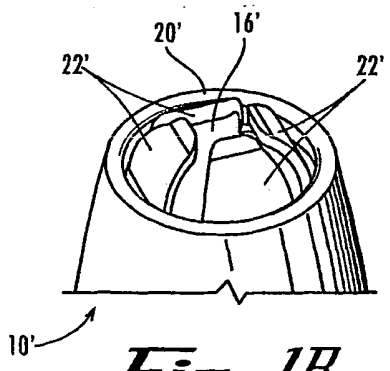


Fig. 1B

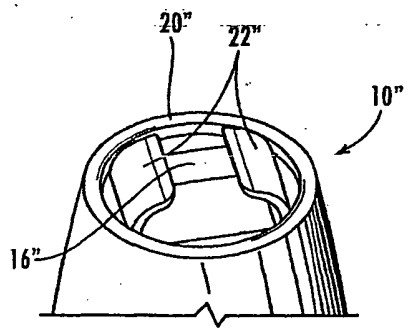


Fig. 1C

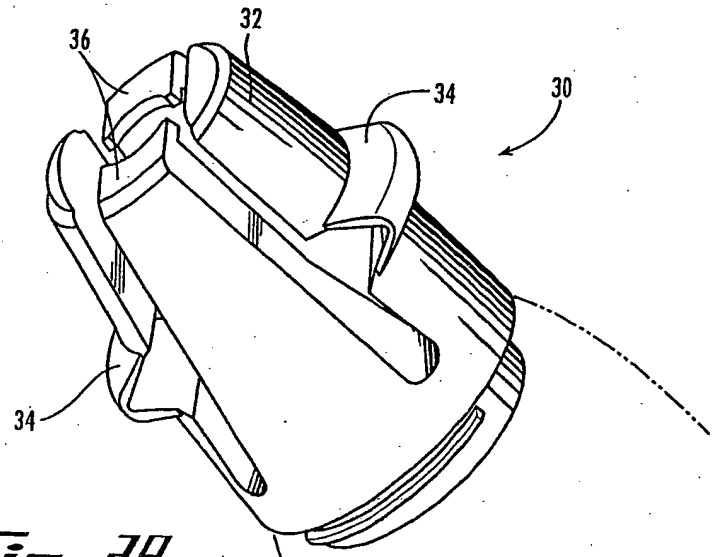


Fig. 2A

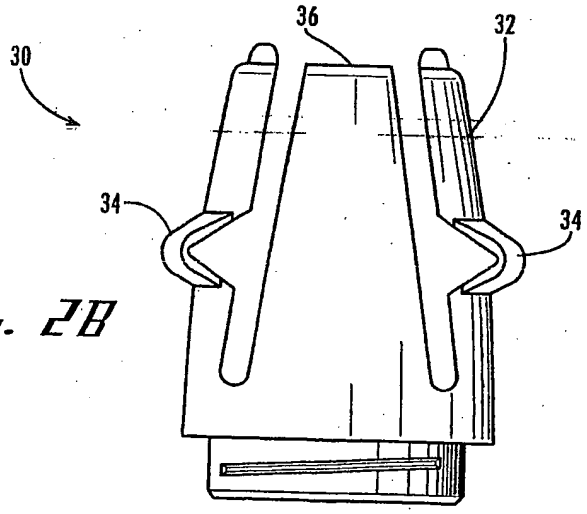


Fig. 2B

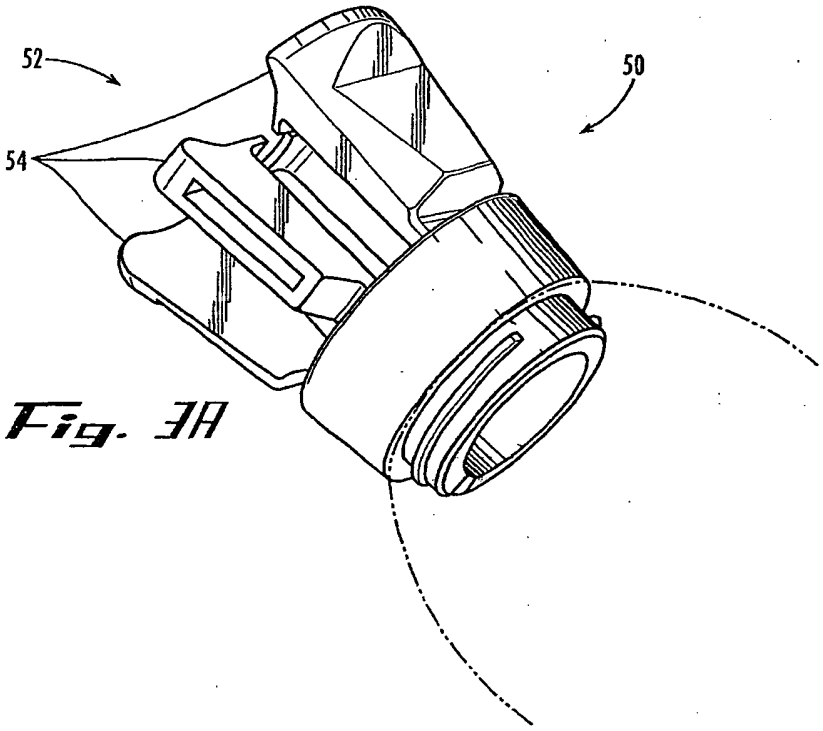


Fig. 3A

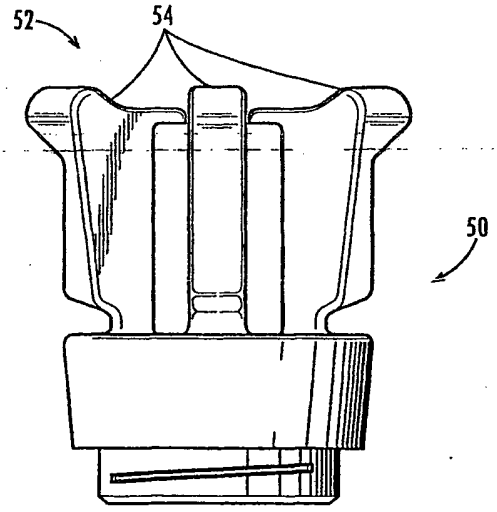


Fig. 3B

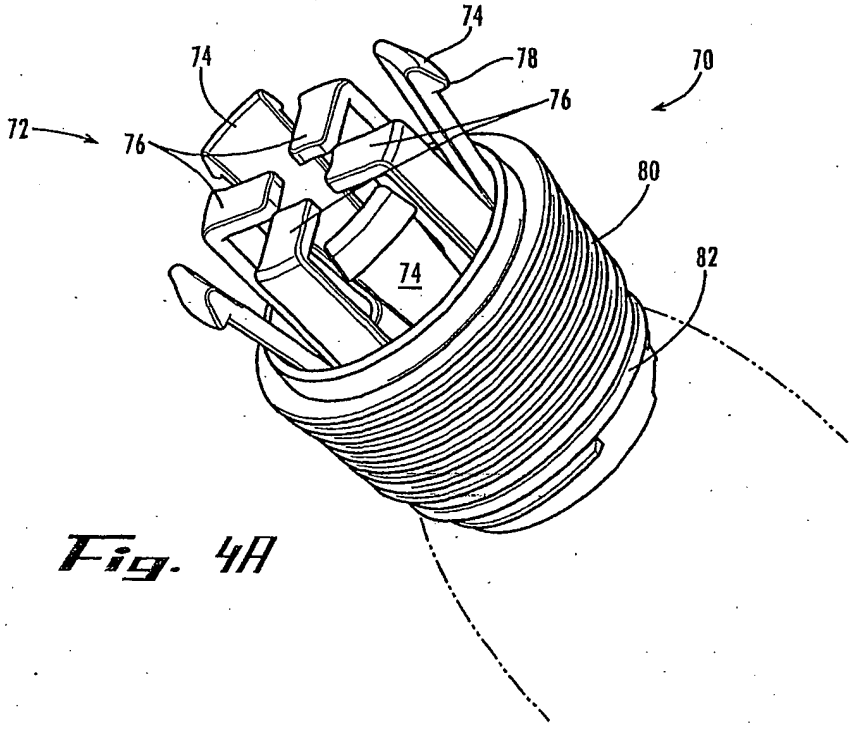


Fig. 4A

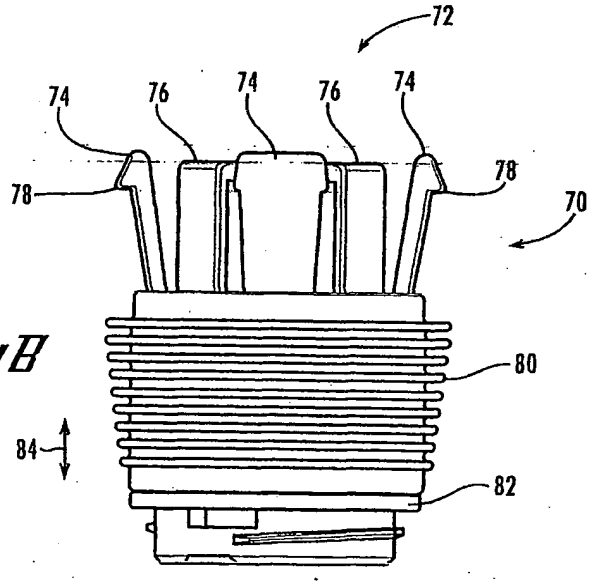


Fig. 4B

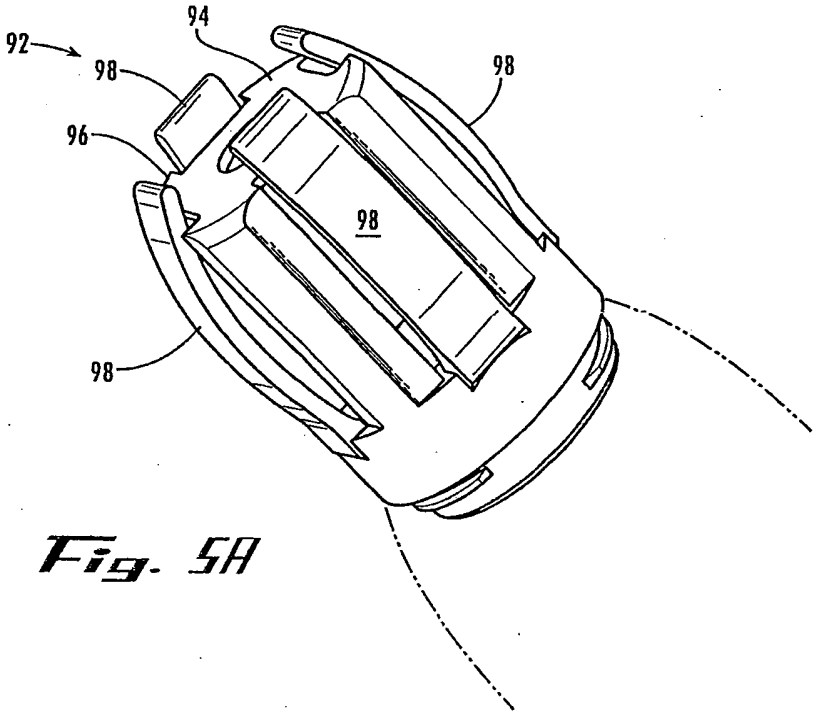


Fig. 5A

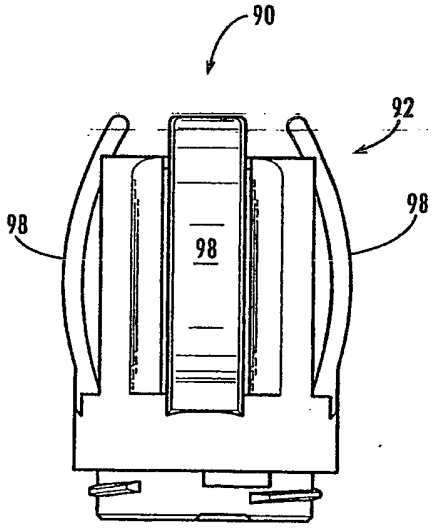


Fig. 5B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/24280

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61B 17/32
US CL : 606/181
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/181

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
East: lancet, needle, syringe, pinch

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0016606 A1 (MOERMAN) 07 February 2002 (04.02.2002), See entire document.	1, 2, 7, 13, 14, 19, 20
X	US 6,409,706 B1 (LOY) 25 June 2002 (25.06.2002), See entire document	1, 5, 7, 11, 13, 16, 18-20
A	US 5,295,972 A (MISCHENKO) 22 March 1994 (22.03.1994), See entire document.	
A	US 4,735,618 A (HAGEN) 05 April 1988 (05.04.1988), See entire document.	
A	4,935,013 A (HABER et al) 19 June 1990 (19.06.1990), See entire document.	
A	US 5,250,031 A (KAPLAN et al) 05 October 1993 (05.10.1993), See entire document.	
A	US 5,304,192 A (CROUSE) 19 April 1994 (19.04.1994), See entire document.	
A	US 5,630,803 A (TAMARO) 20 May 1997 (20.05.1997), See entire document.	

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family.

Date of the actual completion of the international search	Date of mailing of the international search report
21 January 2005 (21.01.2005)	14 FEB 2005
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Glenn Dawson Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet) (January 2004)

THIS PAGE LEFT BLANK

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☑ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.
As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE LEFT BLANK